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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/728,337

12/03/2003

Marguerite A. Cervin

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7590

12/30/2005

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EXAMINER

AKHAVAN, RAMIN

ART UNIT

PAPER NUMBER

1636

DATE MAILED: 12/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/728,337	Applicant(s) CERVIN ET AL.	
	Examiner Ramin (Ray) Akhavan	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12/03/2003.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-48 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121 (each group designated by a Roman numeral as follows):

- I. Claims 13, 32 and 40, drawn to bacterial cells transformed with *a DNA construct* comprising a promoter inserted upstream of a glucose assimilator, classified in class 435, subclass 252.1.
- II. Claims 33, 42-44 and 48, drawn to bacterial cells transformed with *two DNA constructs*, classified in class 435, subclass 252.1.
- III. Claims 1-12 and 26-27, 30-31, drawn to a method of *increasing carbon flow* in a bacterial host requiring genetic modification *with a DNA construct*, classified class 435, subclass 6.
- IV. Claims 22-25, drawn to a method of *increasing carbon flow* in a bacterial host requiring genetic modification with a *first and second DNA construct*, classified in class 435, subclass 6.
- V. Claims 14-21, drawn to a method of *increasing production of a desired product* in a host cell transformed with *a single DNA construct*, classified in class 435, subclass 69.1.
- VI. Claims 46-47, drawn to a method of *increasing production of a desired product* in a host cell transformed with *two DNA constructs*, classified in class 435, subclass 69.1.
- VII. Claims 34-39, drawn to a method of *increasing phosphoenolpyruvate (PEP)* availability, classified in class 435, subclass 6.
- VIII. Claims 41 and 45, drawn to a method of *increasing growth rate* in a bacterial cell, classified in class 435, subclass 471.

The claims encompass 8 distinct inventions. As a preliminary matter, it must be noted that claims 28-29 are linking claims, as to Groups III and IV. The restriction requirement for the linked inventions is subject to the nonallowance of the linking claim(s). Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn

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and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application.

Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Generally, the inventions are directed to products that are modified on a patentably distinguishable basis, as well as processes that are biologically and patentably distinct. The inventions are biologically and patentably distinct based on genetic modification with *one* or *two DNA constructs*, as well as based on distinct action steps directed to different effects and functions, as is further discussed herein below.

Groups I and II are patentably distinct. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions encompass products, i.e., bacterial host cells, where each group invention is distinguished based on the number of modifications (i.e., a single versus double genetic modification), as well as the characteristics of the modification (i.e., particular DNA construct). Thus, Group I is defined by a single integration of a DNA comprising a promoter upstream of a glucose assimilation protein, while Group II is defined by cells transformed with a promoter

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upstream of a glucose transporter or transformed with a second construct comprising a promoter upstream of a glucokinase gene. As such, a search of the non-patent literature for one host cell would not necessarily yield the other, because each cell composition is defined by a different genetic modification.

Groups III-VIII are unrelated as amongst each other. The inventions are directed to processes that result in biologically distinct outcomes or effects (i.e., Groups III/IV, V/VI, VII and VIII). With respect to Groups III/IV and V/VI, while the inventions may be directed to the same result/effect, the processes involve distinct modes of operation (i.e., genetic modification with one DNA construct versus genetic modification with a first and second DNA constructs). Therefore, each invention is defined either by a distinct function or effects, or different modes of operation.

As between the products (Group I and II) and processes (Groups III-VIII), the inventions are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the host cells can be used in distinct or materially different processes (e.g., for maintaining and propagating plasmid vectors). As such, searching for a product would not necessarily yield a particular process.

However, where the examiner has required restriction between product and process claims, if applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance,**

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whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

Because these inventions are distinct for the reasons given above and the search required for each group would pose an undue burden if the groups were examined together thus restriction for examination purposes as indicated is proper. Notwithstanding traversal, Applicant must elect a single group from Groups I-VIII for examination for a response to this restriction to be considered complete.

For the reasons given above these inventions are distinct and have acquired a separate status in the art as shown by their different classification. In addition each group would require a separate search, thus restriction for examination purposes as indicated is proper. Applicant is advised that a reply to this restriction requirement must include an election for the invention (i.e. Group I or II or III, etc.) to be examined, for the reply to be complete, notwithstanding that the requirement be traversed (37 CFR 1.143). Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR

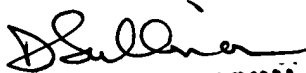
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1.48(b) if none or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ramin (Ray) Akhavan whose telephone number is 571-272-0766. The examiner can normally be reached on Monday- Friday from 8:00-5:30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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DANIEL M. SULLIVAN
PATENT EXAMINER